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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,646	11/16/2005	David G. Quinn	5935/117	1392

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/529,646

Applicant(s)

QUINN, DAVID G.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 and 22-32 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 1/22/2007 in which claims 1-16 and 20-21 were cancelled, claims 17-19, 22-23 and 26-28 were amended, and claim 32 was added. Currently claims 17-19 and 22-32 are pending for examination in this application.

Claim Objections

Claim 24 is objected to because of the following informalities: The claim depends from claim 23, which depends from claim 22; the instant claim refers to a bolus tip, which has a lack of antecedent basis in the preceding claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 22-24, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. (5,421,826). Crocker et al. discloses a drug delivery and dilation catheter having a reinforced perfusion lumen.

Regarding claims 17, 22-24, 30 and 32, Crocker et al. discloses a catheter (74) capable of delivering/removing fluid from a body cavity comprising a multiple lumen tube (78) containing first and second lumens (14, 52) that terminate at different points due to

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a terminating separating septum (15) with a first bolus (32) that is independently formed with a nose end and connector end having an axial passage there through (Figure 7), and a single lumen catheter tube (75) separate from the multiple lumen catheter tube seated in the nose end of the bolus (Figures 6-10).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-25, 30, 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Work et al. (2003/0069534). Work et al. discloses a catheter for continuous flow.

Regarding claims 22-25, 30 and 32, Work et al. discloses a catheter (10) capable of delivering/removing fluid from a body cavity comprising a multiple lumen tube (or first tube arrangement) (12, 14) containing first and second lumens (14, 24) that terminate at different points due to a terminating separating septum with a first bolus (or connecting member) (34) that is independently formed with a nose end (84) and connector end (82) having an axial passage there through (Figure 4), and a single lumen catheter tube (second catheter tube arrangement) with a cylindrical wall (14) seated in the nose end of the bolus (84) with side ports (Figure 8) (Figures 2A-2D, 3 and 5A-5B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-19, 22-25, and 30-32 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (5,056,091) in view of Work et al. (2003/0069534).

Regarding claims 17-19, 22-25, and 30-32, Anderson discloses a (Figure 1 and 5-6) a first feeding tube (10) attached to a first bolus (12) (which can be hollow or solid) and act as a plug with a nose end and connector end with an outlet port (14) fluidly connected to the first tube lumen, said bolus being formed independently of the catheter tube with a single lumen catheter tube (16) separate from the first lumen tube seated in an axial passage of the bolus with a second bolus (18) at the distal end of the second bolus with is operable to have a port located in its side and has a bullet shaped nose (col 3) (Figures 1 and 5-6).

Anderson meets the claim limitations as described above except for a first multiple lumen tube.

However, Work et al. teaches a catheter for continuous flow.

Regarding claims 17-19, 22-25 and 30-32, Work et al. teaches discloses a catheter (10) capable of delivering/removing fluid from a body cavity comprising a multiple lumen tube (or first tube arrangement) (12, 14) containing first and second lumens (14, 24) that terminate at different points due to a terminating separating septum with a first bolus (or connecting member) (34) (Figures 2A-2D, 3 and 5A-5B).

At the time of the invention, it would have been obvious to add the multiple lumen tube of Work et al. to the system of Anderson in order to provide a dedicated lumen for catheter tracking or a lumen for separate fluid introduction or removal. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Work et al. ([0007-0013]).

Claim Rejections - 35 USC § 103

Claims 26-29 are rejected under 35 U.S.C 103(a) as being unpatentable over Anderson (5,056,091) in view of Work et al. (2003/0069534) in further view of Martin et al. (5,195,962). The modified Anderson meets the claim limitations as described above except for a cylindrical shaped plug.

However, Martin et al. teaches a triple lumen catheter.

Regarding claims 26-29, Martin et al. teaches the use of end plugs (56,60) within a multiple lumen catheter (Figures 2-5).

At the time of the invention, it would have been obvious to include the end plugs of Martin et al. to the system of Cruz et al. in order to direct the lumen flow or to close the lumen off to port flow through the catheter elongate body. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Martin et al.

Response to Arguments

Applicant's arguments with respect to claims 17-19 and 22-32 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendments.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Quinn (5,451,216)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/28/07


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